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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,476	07/02/2003	Patrick T. Prendergast	802_004 CON	7731

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,476

Applicant(s)

PRENDERGAST ET AL.

Examiner

Raymond J. Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 21, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 21,30-62 and 65-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20,22-29,63 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

CLAIMS 1-71 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment filed June 21, 2005 has been received and entered into the application. Accordingly, claims 6, 15, 16, 63 and 64 have been amended. In view of such amendments, the claim objections set forth in the previous Office action dated December 21, 2004 are withdrawn.

Election/Restriction

This application contains claims 21, 30-62 and 65-71 drawn to an invention nonelected with traverse in the Reply filed November 19, 2004. A complete reply to this final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's election with traverse of Group I (claims 1-44 and 62-64) and election of oltipraz as the species of active agent; compounds which chelate with, or form a complex with, one or more divalent or trivalent metal ions as a subgenus within the group of compounds recited in claim 1; and neurodegenerative diseases as the therapeutic use in the reply filed on November 19, 2004 is again acknowledged and remains as the basis of the present examination. For the reasons above and of record, the restriction requirement is still deemed proper and therefore remains **FINAL**.

Claims 21, 30-62 and 65-71 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

The claims corresponding the elected subject matter are 1-20, 22-29, 63 and 64 and such claims are herein acted on the merits. The species of the therapeutic objective that is herein

Art Unit: 1614

examined is “a degenerative disorder, a neurodegenerative disorder, a degenerative-related disorder, a neurodegenerative-related disorder”. While Applicants have elected neurodegenerative disorders as the species, the Examiner has expanded the scope of this species to include those species which represent a single grouping of therapeutic objectives which are patentably distinct from the other claimed therapeutic objectives.

Claim Rejection - 35 USC § 112, Second Paragraph

Claims 1-6, 8-23, 25-29, 63 and 64 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons of record as set forth in the previous Office action.

Applicants’ arguments pertaining to the term “degenerative” are deemed persuasive and thus, this rejection no longer applies to this term. Also, because the term “use” has been deleted from claims 63 and 64, this ground of rejection has also been withdrawn.

The term “related”, however, remains indefinite. It remains that the claims and the specification does not provide a standard for ascertaining the requisite qualitative nature of the “relationship” such that one of ordinary skill in the art would be reasonably apprised of what degenerative disorders, other than those expressly set forth, are intended to be covered by the present claims. Absent such a standard, the term “related” would invite subjective interpretations as to the metes and bounds of the subject matter of the present claims which is not proper under 35 U.S.C. § 112, second paragraph.

Applicants’ arguments at pages 22 and 23 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination.

Art Unit: 1614

Applicants have argued that based on conventional knowledge in the art, one skilled in the art would be reasonably apprised of the metes and bounds of the claimed subject matter. Applicants have not, however, pointed to any particular "conventional knowledge in the art" that would place an objective standard to the subjective term "related".

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20, 22-29, 63 and 64 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating or slowing the progression of a degenerative or neurodegenerative disorder, does not reasonably provide enablement for the prevention of a degenerative or neurodegenerative disorder.

This rejection is maintained for the reasons of record as set forth in the previous Office action dated December 21, 2004 at pages 8-11.

Applicants' arguments at pages 23-24 of the amendment have been carefully considered, but fail to persuade the Examiner of error in his determination.

In essence, Applicants have argued that because the requirement of 35 U.S.C. § 101 have been met, the rejection should be withdrawn. In particular, Applicants have urged that in the present case, "there is no underlying logic made by the present applicant that is seriously flawed, and that the facts upon which the assertions of the utility of the present invention is based are not inconsistent with such logic. Moreover, it is submitted that in order for the present invention to

function as disclosed, no scientific generally accepted scientific principles would be violated” (amendment at page 24).

This fails to persuade the Examiner of error because the present rejection is based on whether or not the claimed subject matter is enabled and not whether the invention has utility.

The Examiner has advanced reasons doubting the accuracy of the statements that a degenerative or neurodegenerative disorder can be prevented.

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

“[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling.” (emphasis added).

Here, Applicants have not come forth with suitable proofs indicating that the teachings contained in the specification are truly enabling.

Accordingly, the rejection is deemed to remain proper.

Claim Rejections - 35 USC § 102

I Claims 1-20, 22-29, 63 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Shapiro (U.S. Patent No. 5,668,117, cited by Applicants), already of record, for the reasons of record as set forth in the previous Office action dated December 21, 2004 at pages 16-17.

Applicants’ arguments at pages 24-25 have been carefully considered, but fail to persuade the Examiner of error.

Art Unit: 1614

In particular, Applicants have not stated that the Examiner has not found each and every element of the present claims disclosed by Shapiro. Rather, Applicants have argued that because oltipraz is disclosed as a co-agent together with a carbonyl trapping agent, such does not disclose the present subject matter.

The Examiner cannot agree that the claims are not anticipated, however, because the present claims recite the term "comprising" and thus are open to the inclusion of the additional agents of Shapiro.

Accordingly, the claims are properly rejected.

II Claims 1-20, 22-29, 63 and 64 remain rejected under 35 U.S.C. 102(b) as being anticipated by Schneider et al. (WO 98/27970, cited by Applicants), Stedman's Medical Dictionary and Remington's Pharmaceutical Sciences ("Remington's", cited by the Examiner), each of record, for the reasons of record as set forth in the previous Office action dated December 21, 2004 at pages 17-20.

Applicants' arguments at page 25 of the amendment have been carefully considered, but fail to persuade the Examiner of error in his determination.

In particular, Applicants have not argued that Schneider et al. fail to teach each and every element of the present claims. Rather, Applicants have argued that because one would have to choose from the disclosed diseases and compounds, anticipation is not present.

The Examiner cannot agree with applicants because each of the claimed diseases and compound, e.g., oltipraz, are disclosed in such a manner to have placed the claimed subject matter in the possession of the public. That is, the diseases and compound disclosed are sufficiently limited or well delineated to direct one to the presently claimed subject matter. Also,

Art Unit: 1614

“A genus does not always anticipate a claim to a species within the genus. *However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named.*” (emphasis added)(see MPEP § 2131.02).

Accordingly, the claims are deemed properly rejected.

Claim Rejection - 35 USC § 103

Claims 1-20, 22-29, 63 and 64 remain rejected under 35 U.S.C. 103(a) as being unpatentable over either of Shapiro or Schneider et al. in view of Girjavallabhan et al. (U.S. Patent No. 5,559,133, cited by the Examiner), each of record, for the reasons of record as set forth in the previous Office action dated December 21, 2004 at pages 20-22.

Applicants' arguments at pages 25-26 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination.

In particular, Applicants have argued that Girjavallabhan et al. does not overcome the alleged shortcomings of Shapiro '117 or Schneider (i.e., “WO '970), (amendment at page 26).

The Examiner maintains that both Shapiro and Schneider have been properly applied under 35 U.S.C. § 102 above and § 103 here and that for the purposes relied on, the combination of Shapiro, Schneider and Girjavallabhan et al. clearly render obvious the claimed subject matter.

Accordingly, the claims remain properly rejected.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


Art Unit: 1614

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

July 16, 2005